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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,667	02/15/2002	Ralph Scannell	98,710-B	5122
7590	04/30/2004			
McDonnell Boehnen Hulbert & Berghoff 300 South Wacker Drive Chicago, IL 60606			EXAMINER OWENS, AMELIA A	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/937,667

Applicant(s)

SCANNELL ET AL.

Examiner

Amelia A. Owens

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-10 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21,23 is/are allowed.
- 6) ☒ Claim(s) 1 and 13-15 is/are rejected.
- 7) ☒ Claim(s) 2,4, 11, 12 and 16-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-21 are pending.

#### *Drawings*

Applicants state that 9 sheets of drawings were filed with the application. However, no drawings are present. Please supply the drawings.

#### *Election/Restrictions*

Applicant's election without traverse of Group I, compounds where G' is carbon in Paper No. dated January 23, 2004 is acknowledged.

The election is deemed without traverse because no arguments were presented.

Claims 3, 5-10 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. dated January 23, 2004.

#### *Priority*

This application claims priority to a PCT. Please insert the continuation data into the specification.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims use the phrase 'metabolically cleavable group' which is indefinite. It is suggested that the term be deleted or replaced by the specific groups applicant intends.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds where G' is C=C; V is di or tri-valent arene; R1/R2 together n is only 2, does not reasonably provide enablement for G' being CH-CH; V being heteroarene, or heterocycle when G' is C=C; n being other than 2 when R1/R2 together. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 14 and 15 are included in the rejection because they contain V(Z)t being heteroarene/heterocycle, specifically furylene or oxolanylene.

**The nature of the invention:** The nature of the invention is to compounds of the formula I where G' is C=C.

**The state of the prior art:** The state of the prior art is that it involves various process to prepare compounds similar to those of the invention. See USP 4,282,233 examples 1-5; and USP 5,438,062 column 6 line 9 thru column 7 line 17.

**The predictability in the art:** It is noted that chemical process are complex and often unpredictable.

**The presence or absence of working examples:** Compounds according to the invention are exemplified by compounds 10, 32, 53, 61, 73, 74.

**The amount of direction or guidance present:** The guidance present in the specification is that compounds made are not commensurate in scope with the claims.

**The breadth of the claims:** The claims are drawn to the compound of claim 1 where G' is CH-CH or C=C.

**The quantity of experimentation needed:** The quantity of experimentation needed is undue. One skilled in the art would need to determine how to make compounds where G' is CH-CH. It is noted that the prior art also teaches compounds where the G' position is C=C.

**The level of the skill in the art:** The level of skill in the art is high. However, there is unpredictability in the chemical arts in preparing the compounds.

Thus, the specification fails to provide sufficient support of the broad compounds of claim 1. As a result necessitating one of ordinary skill to perform an exhaustive search for which methods to prepare compound of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion"

and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test how to prepare the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the subject matter from the claims.

#### ***Claim Objections***

Claims 2, 4, 11, 12, 14-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Allowable Subject Matter***

Claims 21 and 23 are allowable to the extent they are limited to the scope of claim 1. The prior art of record does not teach or fairly suggest the claimed composition or method of treating asthma.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690.

The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens  
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Art Unit 1625